IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

PUREWICK CORPORATION, Plaintiff/Counterclaim Defendant, v. SAGE PRODUCTS, LLC, Defendant/Counterclaim Plaintiff.	)	C.A. No. 19-1508-MN

PLAINTIFF'S ANSWERING BRIEF IN OPPOSITION TO DEFENDANT'S MOTIONS FOR JUDGMENT AS A MATTER OF LAW AND NEW TRIAL, AND CONDITIONAL MOTION TO AMEND THE JUDGMENT

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I. INTRODUCTION

Sage's post-trial motions are premised on factual disputes, waived arguments, and baseless claims of "prejudice." Sage repeatedly asks the Court to consider only Sage's evidence, or only evidence from PureWick's case-in-chief. But, at this stage, the Court must consider ***all the evidence*** and, under the proper legal standard, Sage's motions should be denied.

II. LEGAL STANDARDS

Judgment as a matter of law ("JMOL") may be entered if the Court "finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on [an] issue." Fed. R. Civ. P. 50(a)(1). JMOL is appropriate "only if, viewing the evidence in the light most favorable to the nonmovant and giving it the advantage of every fair and reasonable inference, there is insufficient evidence from which a jury reasonably could find liability." *Lightning Lube, Inc. v. Witco Corp*., 4 F.3d 1153, 1166 (3d Cir. 1993). JMOL is a remedy to be invoked only "sparingly." *CGB Occupational Therapy, Inc. v. RHA Health Servs. Inc*., 357 F.3d 375, 383 (3d Cir. 2004).

The Court has discretion whether to grant a new trial. *Lightning Lube,* 4 F.3d at 1167. "[N]ew trials because the verdict is against the weight of the evidence are proper only when the record shows that the jury's verdict resulted in a miscarriage of justice or where the verdict, on the record, cries out to be overturned or shocks [the] conscience." *Williamson v. Consol. Rail Corp.*, 926 F.2d 1344, 1353 (3d. Cir. 1991).

III. SAGE ERRONEOUSLY ASSERTS THAT THE COURT CAN ONLY CONSIDER EVIDENCE FROM PUREWICK'S CASE-IN-CHIEF

Throughout its brief, Sage erroneously asserts that the Court may only consider evidence from PureWick's case-in-chief when assessing the sufficiency of evidence. *See, e.g.,* D.I. 332 at 25 ("no evidence of copying in its case-in-chief.") (emphasis in original). Rule 50, however, "establishes two stages for [challenging the sufficiency of the evidence] – prior to submission of

the case to the jury, and after the verdict and entry of judgment." *Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc.*, 546 U.S. 394, 399 (2006). Under Rule 50(b), after the verdict, the standard is whether the movant can show that "the jury's findings, presumed or express, are not supported by substantial evidence or, if they were, that the legal conclusion(s) implied [by] the jury's verdict cannot in law be supported by those findings." *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1348 (Fed. Cir. 1998) (alteration in original). Substantial evidence is "such relevant evidence ***from the record taken as a whole***." *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 893 (Fed. Cir. 1984); *see also Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000) (for JMOL motions, "the court should review ***all of the evidence in the record***").[1]

And Sage's position is odd given its request that the parties only examine each witness once, rather than calling the same witness in each party's case-in-chief. *See* D.I. 296 at 28:4-15. The Court confirmed that it preferred this procedure. *Id.* at 29:17-22. As a result, both parties restricted examination of the trial witnesses to one time and PureWick did not call Sage's witnesses in its case-in-chief or present deposition testimony of the same witnesses multiple times.[2]

IV. SAGE IS NOT ENTITLED TO JMOL OR A NEW TRIAL ON INFRINGEMENT

A. Substantial Evidence Supports The Jury's PrimaFit Infringement Verdict

Dr. John Collins[3] carefully and methodically testified that PrimaFit meets every element of '376 patent claims 1, 5, and 9, and that use of PrimaFit meets each step of '989 patent claims 1 and 6. Trial Tr. at 446:13-471:25. Dr. Collins also testified that Sage directly and indirectly infringes these claims. *Id.* at 472:1-474:11. Dr. Collins' testimony was supported by citations to

[1] All emphasis added throughout the brief, except as otherwise noted.

[2] Although Sage is incorrect re the standard of review, PureWick presented sufficient evidence during its case-in-chief to support the jury's findings.

[3] Dr. Collins has a Ph.D. in Mechanical Engineering from MIT, and decades of experience in medical device design and development. Trial Tr. at 425:14-428:17.

documentary evidence, including Sage's engineering drawings and reports, marketing materials, and physical PrimaFit samples. *Id.* at 446:13-24.

Sage simply ignores this evidence. Sage contends that there was no substantial evidence of (1) direct infringement of the '989 patent claims, (2) literal infringement of any claim, or (3) indirect infringement. Sage also contends that PureWick proved infringement by comparing the PrimaFit with patent figures and the PureWick product. None of these arguments have merit.

1. Direct Infringement of the '989 Patent By Sage And Its Customers

Sage argues that PureWick has no evidence of direct infringement for the '989 patent. D.I. 332 at 4. According to Sage, PureWick must show "specific instances of direct infringement" and that PureWick's reliance on the PrimaFit IFU did not suffice because "there is no evidence that anyone actually followed the IFU." D.I. 332 at 5. Sage is wrong. As the Federal Circuit recently stated, "where an alleged infringer designs a product for use in an infringing way and instructs users to use the product in an infringing way, there is sufficient evidence for a jury to find direct infringement." *C.R. Bard Inc. v. AngioDynamics, Inc.*, 979 F.3d 1372, 1379 (Fed. Cir. 2020). This evidence suffices "even when there is no direct evidence of a specific person doing so." *Id.*[4]

Here, substantial evidence showed that Sage designed PrimaFit to be used in an infringing manner. *See, e.g.*, PTX-597.2 (describing PrimaFit "design origin and evolution"); PTX-486.12, 19; PTX-42; Trial Tr. at 401:7-16 (Dr. Yun's testimony on how PrimaFit is used with patients). The record also established that Sage provided hospitals with the PrimaFit IFU on product packaging and that Sage trains hospital personnel to use PrimaFit in accordance with the IFU. *See* PTX-34; JTX-14; Trial Tr. at 692:23-693:1; *see also* Trial Tr. at 339:1-4, 363:25-364:4, 691:20-

[4] *See also Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 843 F.3d 1315, 1335 (Fed. Cir. 2016) (circumstantial evidence of inducement "directed to a class of direct infringers" suffices "without requiring hard proof that any individual third-party direct infringer was actually persuaded to infringe by that material.")

693:6. Use of the PrimaFit in accordance with the IFU infringes the '989 claims. Trial Tr. at 452:6-12, 459:10-460:10, 469:1-470:1. Finally, Sage has sold thousands of PrimaFits to hospitals since the '989 patent issued. DTX-199 (showing Sage's sales to hospitals). Thus, there was ample to find direct infringement by Sage's customers. *See Power Integrations,* 843 F.3d at 1335. The evidence also sufficed for the jury to conclude that Sage directly infringed. Its employees conducted PrimaFit trials at hospitals and trained hospital personnel after the '989 patent issued in August 2019. Trial Tr. at 472:5-20, 692:23-693:9; PTX-53; JTX-3 ("'989 Patent").

Sage also argues there is no evidence that a "single entity" performed each method step.[5] D.I. 332 at 4-5. But nothing about claim 1 would implicate two persons performing the recited method steps ("disposing in operative relationship," "allowing urine," and "allowing the received urine"), and PureWick has never alleged divided infringement. Moreover, the Federal Circuit recently rejected this exact argument, finding that when a medical device maker sells its device to a hospital the patentee need not prove that a single person performs every step of a claimed method. *Bard*, 979 F.3d at 1379-80. This is because, even if multiple persons at the hospital perform the various method steps, they do so "as part of the same 'entity' [the hospital]." *Id.*

2. Literal Infringement Of The '376 And '989 Patents

(a) "the fluid permeable support is distinct from and at least proximate to the fluid reservoir"

Sage argues that "[n]o reasonable jury could find that PrimaFit has a 'support [that] is distinct from and at least proximate to the fluid reservoir.'" D.I. 332 at 5. Dr. Collins testified that this limitation was met, and the jury credited that testimony. Specifically, he identified the "inner batting material" as the support and explained that "there is a reservoir area to accumulate liquid

[5] Sage also argues that it "requested a jury instruction on single-entity infringement, which was denied." D.I. 332 at 5, n.2. Sage, however, failed to preserve such an objection when it agreed to the Court's proposed changes to the instructions on this issue. Trial Tr. at 1002:14-1004:18.

which is distinct from, different from the inner batting or the fluid permeable support, but it's also next to it." Trial Tr. at 457:3-6. The jury also saw engineering drawings (PTX-116), PrimaFit development presentations (PTX-538; DTX-772), and physical samples (JTX-14) where they could assess the relationship between PrimaFit's "support" and its "reservoir."

The jury was entitled to find this element was met based on Dr. Collins' testimony and the documentary and physical evidence. *See, e.g.*, *WCM Indus., Inc. v. IPS Corp.*, No. 13-CV-02019, 2016 WL 2755464, at *3 (W.D. Tenn. May 11, 2016) (evidence sufficient to defeat JMOL motion included "physical samples of the products, which they could assemble and disassemble in their evaluation of the claims"); *Stryker Trauma S.A. v. Synthes (USA),* No. 01-CV-3879, 2007 WL 1959235, at *4 (D.N.J. June 29, 2007) (finding jury's access to the accused products and expert testimony sufficed to support infringement verdict).

Sage does not dispute this evidence. Instead, Sage asserts an untimely, new, and incorrect claim construction argument. Sage argues, based on portions of the prosecution history not in evidence,[6] that the recited reservoir cannot "include" or "contain" any portion of the permeable support. Sage then argues that "[n]o reasonable jury could find PrimaFit satisfies the limitation because the reservoir in PrimaFit ***does include*** and ***does contain*** the support." D.I. 332 at 6 (emphasis in original). However, Sage never previously advanced such a construction and, accordingly, it was waived. *Lazare Kaplan Int'l, Inc. v. Photoscribe Techs., Inc.*, 628 F.3d 1359, 1376 (Fed. Cir. 2010) (claim construction argument waived if first raised post-trial).

This proposed construction also is contrary to the intrinsic record. The specification shows embodiments where the support extends into the area Sage designates as the reservoir. '989 Patent

[6] Sage cites to JTX-5 at 424 and JTX-6 at 587-88, which are not in evidence. D.I. 332 at 6. PureWick cites to the same unadmitted exhibit to rebut Sage's argument, but does not concede that such unadmitted exhibits should be considered.

Fig. 32. Moreover, PureWick distinguished the Kuntz reference at issue on the ground that "the core material of Kuntz ***fills the entire internal space*** within Kuntz's backing layer 36, ***so there is no room for a fluid reservoir*** within the fluid impermeable casing between the fluid permeable support and the fluid impermeable casing." Def. Ex. 18 at JTX-6.587. In contrast, PureWick noted its "specification discloses that the fluid reservoir is a ***gap or void space*** between materials." *Id.* at JTX-6.588. Kuntz was distinguished because it had no "void space" for fluid to accumulate. That is different from the claimed invention, as well as the infringing device. The PrimaFit clearly includes a void space to accumulate urine proximate to the support. Trial Tr. at 456:21-457:6.

(b) "longitudinally elongated opening"

Sage argues that PrimaFit does not have a casing defining a longitudinally elongated opening because "[t]here is fabric sewn to the foam back, creating a physical barrier without an opening." D.I. 332 at 7. But the claims require an opening in the fluid impermeable casing ***for fluid entry***, not for a physical structure such as a finger. As Dr. Collins explained, the opening allows a fluid (urine) to enter the otherwise impermeable casing. *See, e.g.*, Trial Tr. at 455:9-14 ("[Y]ou need to have an opening in the impermeable layer to have the fluid be able to get into the device."); *see also id.* at 435:12-15, 436:2-5, 438:13-25. This is how the patent describes the claimed "opening." '989 Patent at 26:7-10. If there were no "opening" in PrimaFit's fluid impermeable casing, the urine could not enter. The fact that a ***permeable*** fabric is sewn to the ***impermeable*** PrimaFit casing does not change that it has an opening for fluid. Indeed, the claims contemplate that a permeable membrane will be "disposed across the elongated opening." JTX-2 ("'376 Patent") at claim 1. The specification likewise discusses embodiments where the permeable membrane is secured to the casing. *See* '376 Patent, Fig. 38, 9:53-58, 13:54-63, 27:10-20.

Sage argues that the patent "describes the casing's opening as a physical opening through which components are inserted and not merely 'open to urine flow.'" D.I. 332 at 7. But Sage

failed to make this argument at trial, and the Court previously rejected this argument during claim construction. *See* D.I. 127 at 77:3-6; D.I. 128 at 12. Indeed, Sage's argument is inconsistent with the patent's description of Figure 38 having "securing portions 1752A and 1752B in combination with the backing portion 1753 [to] define ***an elongated opening 1704A through which a fluid (e.g., urine) can travel into the assembly*** 1702." '376 Patent at 27:14-17. In that "embodiment" components are not inserted through the opening and the backing is made of adhesive tape that is adhered to the permeable membrane. *Id.* at 27:10-11.

(c) "fluid impermeable casing"

Dr. Collins testified that PrimaFit's combined components "act[] as the outer cover of the device as per the Court's claim construction." Trial Tr. at 454:8-9. In contrast, Sage's expert incomprehensibly asserted that "selective components don't add up to a casing. These ***selected components don't exist anywhere***." *See id.* at 771:13-19. The jury was entitled to credit Dr. Collins' testimony over Sage's expert. Sage also argues that the PrimaFit casing is not fluid impermeable because it has vents on the top of the casing and that Mr. Sheldon purportedly "put some fluid in it, and . . . actually observed fluid dripping through these holes." *Id.* at 772:10-13. Mr. Sheldon provided no evidence concerning this alleged test and the jury was entitled to give it no weight. More importantly, as Dr. Collins testified, the use of the same type of vents in a fluid "impermeable casing" is "described actually in the patent." *Id.* at 454:19-455:2.

3. There Was Substantial Evidence of Indirect Infringement

Sage incorrectly argues "PureWick proved neither knowledge of the patents or any intent to infringe." D.I. 332 at 8. But Sage conceded it had knowledge of the patents on the day they issued. *See* Section VI, *infra*. And there is substantial evidence of Sage's knowledge of, and intent to cause, infringement by Sage's customers. Sage designed the PrimaFit to be used in an infringing manner and provided instructions and trained hospitals to use the product in an infringing manner.

See Section IV.A.1, *supra*. And, the jury found that Sage willfully infringed the '376 and '989 patents. The evidence showed Sage deliberately copied the patented inventions and was aware of the issued patents claiming the same inventions, and yet it continued to make, use and sell the infringing PrimaFit and instructing others to use it in an infringing manner. *See Microsoft Corp. v. DataTern, Inc.*, 755 F.3d 899, 905 (Fed. Cir. 2014) ("Providing instructions to use a product in an infringing manner is evidence of the required mental state for inducing infringement."); *Eli Lilly & Co. v. Actavis Elizabeth LLC*, 435 F. App'x 917, 926 (Fed. Cir. 2011) ("[T]he sale of a product specifically labeled for use in a patented method constitutes inducement to infringe that patent, and usually is also contributory infringement.").

4. PureWick Did Not Prove Infringement By Improper Comparisons

Sage argues for a new trial because PureWick allegedly "attempted to prove infringement and improper copying by comparing PrimaFit with patent figures and PureWick's products." D.I. 332 at 8. These prejudice claims ring hollow given that Sage repeatedly argued non-infringement by comparing its product to PureWick. *See* Trial Tr. at 135:22-136:1 ("[T]hey have this opening on the top . . . We don't have an opening."), 152:23-25 ("PrimaFit does not infringe because . . . [w]e do not have a casing like the PureWick."), 773:1-2 ("Can you explain how that's different from the PureWick product?"). Moreover, Sage failed to object at trial to the vast majority of the evidence and arguments it now asserts were improper, including Trial Tr. at 435-48, 1161-65, 1218-19; PDX1.16-18; PDX8.20, 8.58-70. As the Court reminded Sage "[i]f you have an objection, make it. If you don't have an objection, it's waived." Trial Tr. at 385:3-5.

As for the two cited instances where Sage did object (Trial Tr. at 115-116 and 537-39), those objections were properly overruled. The Court overruled Sage's objection during PureWick's opening statement (*id.* at 115:20-116:1) because PureWick's reference to the PureWick and PrimaFit products went to copying, and was "not for infringement." *See id.* at

115:11-116:6. The Court also overruled Sage's objection to counsel's question during Dr. Collins' redirect regarding "what the patent says . . about the elongated opening" (*id.* at 536:25-537:1) because such questioning was not "talking about infringement."[7] *Id.* at 538:24-539:11.

Sage erroneously complains that "PureWick's infringement expert Collins repeatedly interwove discussion of the PrimaFit device, Figures 36 to 38, and the PureWick device." D.I. 332 at 10. But Dr. Collins separately testified as to the disclosure of the patents (Trial Tr. at 430-39), followed by his opinions that the PureWick product is covered by the patents (*id.* at 439-46), followed by his opinions that the PrimaFit infringes (*id.* at 446-71). Dr. Collins then compared the PrimaFit to the asserted claims on an element-by-element basis. *Id.* at 452-62, 467-71. In any event, the Court instructed the jury that for infringement, "you should not compare the accused Sage Products with PureWick's products or the [patent] descriptions or figures." *Id.* at 1112:13-16. The jury is "presumed to have followed the instructions the court gave it." *U.S. v. Givan*, 320 F.3d 452, 462 (3d. Cir. 2003). Thus, there was no prejudice.

Finally, Sage argues that the cited testimony and arguments were not proper evidence of copying. D.I. 332 at 9. To the contrary, evidence that PrimaFit included the same patented features as PureWick's product and embodiments in the patent is plainly relevant to copying. *See Riggs Mktg., Inc. v. Mitchell*, 194 F.3d 1338, at *4 (Fed. Cir. 1999) (patentee's commercial embodiment relevant to willfulness "inasmuch as it might show that RMI copied Mitchell's design"); *Penederm*

[7] Sage suggests that PureWick somehow violated the Court's *in limine* order (D.I. 332 at 9), but fails to note that the Court granted Sage's MIL only with respect to infringement and denied it with respect to copying, stating that "[i]t may be that plaintiff can rely on the at issue comparisons to support other arguments such as copying or lost profit." D.I. 296 at 23:1-7. PureWick understood the "at issue" comparisons to be "side-by-side" comparisons of PrimaFit to PureWick or the patent (*id.* at 22:2), which PureWick never did at trial. Indeed, in the two instances where Sage objected at trial PureWick was not making side-by-side comparisons, and, as noted, the Court properly overruled the objections. Trial Tr. at 115-16, 537-39.

Inc. v. Alzo, Inc., No. C 95-1222-FMS, 1996 WL 724766, at *4 (N.D. Cal. Dec. 6, 1996) ("Copying, either of the patent or a commercial embodiment of the patented invention, provides particularly probative evidence of willful infringement.").[8]

B. Substantial Evidence Supports The Jury's PrimoFit Infringement Verdict

The verdict that PrimoFit infringes the '407 patent was supported. Specifically, Dr. Collins testified that the PrimoFit meets every element of the asserted '407 patent claims. Trial Tr. at 481-95. His testimony was based on inspection of the PrimoFit and substantial documentary evidence, including internal Sage engineering drawings and reports. *Id.* at 482:19-483:2, 483:23-484:6.

1. "Wicking Material"

Dr. Collins testified that the microclimate spun bond layer in PrimoFit includes a hydrophilic treatment and therefore is a wicking material. Trial Tr. at 485:10-486:18; *see also* PTX-98. Dr. Collins also explained that PTX-95 shows that PrimoFit's "ultra soft wicking fabric diverts urine away from the skin." *Id.* at 486:19-487:2. Sage's witness, Brian Ecklund, admitted that Sage designed PrimoFit to "wick[] fluid away from skin" (*id.* at 648:9-650:3; PTX-572.4) and that the microclimate spun bond layer is the material in contact with the patient's skin (*id.* at 650:19-651:1).

And, Mr. Jezzi, an expert with more than 30 years of experience designing and developing incontinence products (*id.* at 939:24-941:18), testified that he conducted wicking tests showing that liquid "wicked through the surface of the PrimoFit spun bond layer" and that "the material was wicking." *Id.* at 947:24-949:5; PTX-760; PTX-763; PTX-764; PTX-767. Mr. Jezzi also

[8] Sage also argues that the Court improperly precluded Sage from suggesting to the jury that the embodiment in Figure 38 does not include a casing because the patent does not refer to it as a casing. D.I. 332 at 11. As the Court recognized, however, the issue was not with "putting up a figure from the patent," it was that Sage was attempting to contradict the Court's claim construction order. Trial Tr. at 534:3-535:2, 538:11-20.

explained why Sage's tests failed to properly assess the wicking issue. Trial Tr. at 950:13-952:1.

Sage asks the Court to credit its expert over PureWick's,[9] but the Court "must presume that the jury credited the testimony of [Dr. Collins and Mr. Jezzi]." *Enplas Display Device Corp. v. Seoul Semiconductor Co., Ltd.*, 909 F.3d 398, 406 (Fed. Cir. 2018).

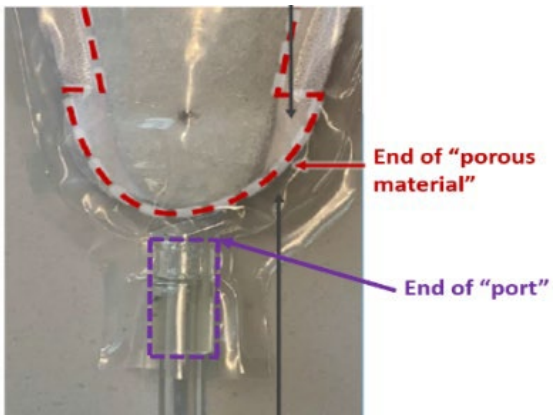
2. "chamber of void space"

Sage makes two arguments why the PrimoFit allegedly does not include a chamber of void space. First, Sage argues that the only evidence this element is met is a single answer by Dr. Collins. This is incorrect. The jury had access to documents and physical samples from which they also could conclude that the PrimoFit has a chamber of void space. Trial Tr. at 407:19-408:1, 643:4-10; *see also WCM Indus.*, 2016 WL 2755464, at *3; *Stryker Trauma*, 2007 WL 1959235, at *4. Sage does not dispute any of this evidence. And Sage does not explain why a single answer from a qualified expert cannot suffice. D.I. 332 at 14-15. The jury was entitled to credit Dr. Collins' opinion in light of the evidentiary record regarding a visible structural feature.

The claim requires "a chamber of void space . . . being defined ***at least partially by*** the second side of the porous material and the flexible layer of impermeable material." JTX-4 ("'407 Patent") at claim 1. Thus, the entire chamber need not be defined by these two layers. If the chamber is partially defined by the porous material and flexible material, the element is met. Dr. Collins pointed to the "extra space" outside of the batting that touches the porous material and the impermeable material. Trial Tr. at 490:12-23. That extra space is defined at least partially by the porous material and impermeable material.

[9] Sage also advances arguments that are unsupported by the record. For example, Sage asserts that "PrimoFit's microclimate material is a water-repellant material," but the cited testimony says nothing about it being "water-repellant." D.I. 332 at 12. Sage also asserts that "[t]he 'ultra soft fabric' in PrimoFit is the jersey fabric . . . not the thin polypropylene microclimate layer." But that likewise is unsupported by the cited documents and testimony. *Id.* at 13.

Sage also argues that PrimoFit does not include a chamber that has a port for receiving a tube because "Claim 1 requires the chamber, formed by the porous layer and impermeable layer, to include the port—not two layers of impermeable material." D.I. 332 at 15 (emphasis in original). Sage mischaracterizes the claim. The chamber need only be defined ***partially*** by the porous material and the flexible layer of impermeable material—meaning that part of the chamber can also be defined by other layers. As shown in the demonstrative on the right (cited in Sage's brief, D.I. 332 at 15), in the PrimoFit product, part of the chamber is defined by the porous material and impermeable material, and part, where the port is located, is defined only by the impermeable material. That is all that the claim requires.



V. SAGE IS NOT ENTITLED TO JMOL OR A NEW TRIAL ON VALIDITY

A. PureWick Did Not Make "Prejudicial" Or "Legally Incorrect" Arguments

Sage asserts that PureWick "argued that the prior art did not result in commercially-available products" in an effort to "leave the jury with the misimpression that to invalidate a patent, prior art must have resulted in a commercial product." D.I. 332 at 16. But Sage cites no instance in which PureWick ever made such an argument. *Id.* To the contrary, PureWick properly relied on the failed efforts of the Wolff/Van Den Heuvel team to establish long felt need and failure of others.[10] PureWick did not simply point to prior art patents or applications as evidence of failure of others, as Sage incorrectly suggests. D.I. 332 at n.9. PureWick showed that the Wolff/Van Den Heuvel team started work in 1999, continued through at least 2006, and failed despite their goal

[10] Likewise, PureWick never argued in its closing that Van Den Heuvel did not qualify as prior art because there was no commercial product. Rather, PureWick addressed failure only in the context of obviousness and noted the "[f]ailure of others." Trial Tr. at 1166:14-22.

of developing a "commercially viable" product. Trial Tr. at 840:6-842:9. This is compelling evidence of non-obviousness. *See, e.g.*, *Janssen Pharmaceutica N.V. v. Mylan Pharm., Inc.*, 456 F. Supp. 2d 644, 671 (D.N.J. 2006). Far from misleading the jury, PureWick explicitly tied this evidence to obviousness during Mr. Sheldon's cross examination, by pointing out his failure to consider it as a "secondary consideration[]" evidencing "failure of others." Trial Tr. at 844:9-25.

Sage also erroneously argues that it was prejudicial for PureWick to introduce evidence concerning Dr. Sanchez's development work. D.I. 332 at 16. Sage's claim that this evidence was presented "[o]ver Sage's objections" is not correct. With the exception of PDX1.22, which was an excerpt from ***joint trial exhibit*** JTX-7 (*see* Trial Tr. at 3:5-20), Sage did not object to any of the cited trial testimony, demonstratives, or arguments. These arguments were thus waived. *InTouch Techs., Inc. v. VGO Comms., Inc.*, 751 F.3d 1327, at n.9 (Fed. Cir. 2014); *Laymon v. Lobby House, Inc.*, 613 F. Supp. 2d 504, 517 (D. Del. 2009). Moreover, Dr. Sanchez is a named inventor on the '376 and '989 patents. Sage's argument that "there was no evidence that Sanchez had any role in the invention of the purportedly novel aspect of the 376/989 patents" (D.I. 332 at 17) is both irrelevant and incorrect. PureWick did not have a burden to prove the contributions of each inventor. And, the claims' novelty lies in their arrangement as a whole, not in some single "aspect." Also, each inventor need not contribute to every aspect of the claim. And Dr. Sanchez continued to exchange ideas with Dr. Newton for years after his original prototype was developed. Trial Tr. at 282:3-6. Sage cannot credibly argue that it was prejudicial for PureWick to present evidence of how the asserted patents and PureWick product came to be.

B. Sage Failed To Prove Invalidity Of The '376 and '989 Patents

Sage argues that JMOL of invalidity of the asserted '376 and '989 patent claims should be granted because its expert, Mr. Sheldon, opined that the Van Den Heuvel reference anticipates or renders obvious those claims, and PureWick did not present a rebuttal witness on those issues.

D.I. 332 at 17-18. Sage asserts that its expert's testimony was unrebutted and thus should control, but the jury was not required to credit his testimony. This was particularly true given that he was discredited on cross-examination. For example, Mr. Sheldon testified on direct that "[t]he Patent Office never reviewed the [Van Den Heuvel] '823 patent application" (Trial Tr. at 811:25-812:4), but conceded on cross that the U.S. counterpart, which has the same disclosure and was cited in Mr. Sheldon's materials considered, was reviewed by the Patent Office. *Id.* at 845:1-858:10.

In addition, as discussed below for all the asserted claims, Sage ignores substantial evidence from which the jury could readily conclude that Van Den Heuvel lacked the "fluid permeable membrane" and "reservoir" limitations and from which the jury could reject Sage's obviousness arguments. Sage also practically ignores the impact of the additional cylindrical claim limitations for claim 5 of the '376 patent and claim 6 of '989 patent.

1. The Jury Properly Rejected Sage's Invalidity Arguments

"[I]t is presumed from a general verdict of patent validity, that the jury found differences between the claimed inventions and the prior art." *Lucent Tech., Inc. v. Newbridge Networks Corp*., 168 F. Supp. 2d 181, 233 (D. Del. 2001). Here, there was substantial evidence from which the jury could conclude that Van Den Heuvel lacked at least the "fluid permeable membrane" and "reservoir" limitations required by all asserted claims.[11]

Mr. Sheldon conceded that Van Den Heuvel does not actually include a "fluid permeable membrane," but that instead he "added it" to the figure in his demonstrative. Trial Tr. 858:11-859:18. For the "reservoir," Mr. Sheldon relied on "tapered end 4" of Van Den Heuvel, but he did not testify that urine could accumulate in that space. Van Den Heuvel describes the function of

[11] The jury also had evidence that the Patent Office did not consider Van Den Heuvel to be the closest art of record and found that none of the cited art disclosed a "fluid permeable support [that] is distinct from and at least proximate to the fluid reservoir." JTX-5a-007-8.

"tapered end 4" as a channel and never once refers to it as a reservoir. DTX-012-0008. Based on either of these two missing elements, the jury reasonably found that Van Den Heuvel did not anticipate and their verdict should be upheld. *Lucent,* 168 F. Supp. 2d at 233 ("[T]he court must uphold the verdict if a reasonable jury could find that one or more elements of the patent claims are not found in the purportedly anticipatory reference.").

With respect to obviousness, Sage did not propose any combination to provide the missing elements of Van Den Heuvel. In addition, Sage wholly ignores evidence of secondary considerations, which "may often be the most probative and cogent evidence of nonobviousness in the record." *Ortho-McNeil Pharma., Inc. v. Mylan Labs., Inc.*, 520 F. 3d 1358, 1365 (Fed. Cir. 2008). The overwhelming evidence of long-felt need, failure of others, and copying (*see, e.g.*, *infra* 12-13 and *supra* 21-23) more than sufficed to reject all of Sage's obviousness arguments.

2. "Cylindrical" Claims: '376 Patent/Claim 5 and '989 Patent/Claim 6

Sage erroneously asserts that PureWick "did not challenge that the dependent claims were anticipated or obvious, i.e., namely because substantially cylindrical designs were well known in the art." D.I. 332 at 18. That is false. PureWick disputed this both during the cross examination of Mr. Sheldon and its closing argument. For example, PureWick's closing addressed this issue, explaining why Mr. Sheldon's proposed obviousness combination of Van Den Heuvel with Coley, which he cited for the cylindrical shape, failed on the record evidence. Trial Tr. at 1177-78.

PureWick also crossed examined Dr. Sheldon on his proposed combination, establishing that Coley disclosed "simply kind of a rolled piece of absorbant material," "didn't disclose a vacuum-assisted pump," and there was "no tube coming out that's drawing urine." *Id.* at 864:17-865:19. Based on this evidence (and consistent with PureWick's closing argument), the jury could conclude there was no reason to combine Van Den Heuvel's device with Coley's non-tube, non-vacuum assisted absorbent material. The jury was also free to reject Mr. Sheldon's opinion that

Van Den Heuvel disclosed the "substantially cylindrical" element of '376 patent claim 5 based on the drawings in Van Den Heuvel that clearly show a cup shape. DTX-12 at Fig. 1.

C. Sage Failed To Meet Its Burden Of Proving Obviousness Of The '407 Patent

Sage argues that Mr. Jezzi's entire rebuttal on the obviousness of the '407 patent claims "focused on whether the top layer was a wicking material rather than whether it would be obvious." D.I. 332 at 18 (emphasis in original). That is incorrect. Mr. Jezzi testified that use of a wicking material in Suzuki was not obvious "because it would defeat the purpose of what they're trying to accomplish which is allow rapid fluid intake into that top layer." Trial Tr. at 944:16-20.

Sage also erroneously argues that "[t]he only disputed issue was whether it would have been obvious to replace Suzuki's top layer with a wicking material." D.I. 332 at 18. Mr. Jezzi also opined that the layer that Sage's expert opined would be a wicking layer in Suzuki is not "disposed on the first side of the flexible layer of porous material" because "there is another material in between" the alleged wicking material and alleged porous material. Trial Tr. at 943:6-11-945:8. Sage does not address this testimony which the jury was entitled to credit.

With respect to '407 patent claim 2, Sage argues that "Jezzi did not address Harvie, Ishii, or Hanifl." D.I. 332 at 19. But ***neither did Sage's expert***. When discussing claim 2, Dr. Newman never mentioned Ishii or Hanifl, and only offered the conclusory statement that "Harvie did this in his patent" without ever pointing to any disclosure. Trial Tr. at 725:13-726:1. Dr. Jezzi explained why it would not have been obvious to replace Suzuki's material with a wicking material and the jury was entitled to credit that testimony.[12] *Id.* at 943:12-944:20.

[12] Sage is wrong that Mr. Jezzi testified that Suzuki "purportedly preferred a non-wicking material." D.I. 332 at 18-19. What he said was it would not have been obvious to replace Suzuki's material with a wicking material because "it would defeat the purpose of what they're trying to accomplish which is allow rapid fluid intake into that top layer." Trial Tr. at 944:16-20.

Finally, Sage argues that PureWick elicited "misleading testimony that Newman had never invalidated a patent." D.I. 332 at 19. That is not the testimony that was elicited. PureWick simply asked whether, prior to her reports in this case, Dr. Newman had submitted opinions as an expert witness on the issue of patent validity, and Dr. Newman testified "[n]o, I have not." Trial Tr. at 742:8-11. That testimony was entirely within Dr. Newman's control. She was not misled.

VI. SUBSTANTIAL EVIDENCE SUPPORTS THE WILLFULNESS VERDICT

Sage argues that no reasonable jury could have found willfulness "based on the evidence in PureWick's case-in-chief."[13] D.I. 233 at 20. As noted above, that is not the test. The Court must assess whether substantial evidence supports the jury's verdict.

Additionally, Sage argues that PureWick's only willfulness evidence occurred before the patents issued, which is irrelevant evidence according to Sage. Sage is wrong for at least three reasons. First, even setting aside the pre-issuance bad behavior, the jury's willful infringement finding is sufficiently supported by substantial evidence that once Sage had knowledge of the patents it had no reasonable defense to infringement. Second, the jury was entitled to take into account all the pre-issuance evidence, including Sage's copying of PureWick's products and unpublished patent application. Third, PureWick did present evidence of Sage's post-issuance conduct, including its deliberate decision to continue marketing and selling its copied/infringing PrimaFit product after learning of the patents on the days they issued.

A. The Willfulness Verdict Is Supported By Sage's Knowledge of the Patents and its Failure to Raise a Reasonable Defense to Infringement

The jury was instructed that it could consider whether Sage had a reasonable basis to

[13] Sage also requests a new trial on willfulness based on PureWick's alleged "inappropriate copying allegations." D.I. 332 at 26. However, PureWick simply showed that Sage had access to PureWick's pending applications and commercial product and that their resulting product incorporated the patented features of these embodiments. That is entirely appropriate copying evidence. Sage's request for a new trial should be denied.

believe that it did not infringe or that the patents were invalid. D.I. 314 at 25. The Court, therefore, must presume that the jury found Sage had no reasonable basis to believe it did not infringe or that the patents were invalid. *SRI Int'l, Inc. v. Cisco Sys., Inc.*, 14 F.4th 1323, 1328 (Fed. Cir. 2021) ("First, we presume, as we must, that consistent with the jury instructions, the jury found that Cisco had no reasonable basis to believe that it did not infringe or that it had a reasonable defense to infringement."). This suffices by itself—even before getting to copying and failure to obtain opinions of counsel—to conclude that substantial evidence supports the jury's willfulness verdict.

The facts here mirror *SRI*. In *SRI*, the Court found that the jury's verdict was supported by evidence that Cisco's invalidity and non-infringement defenses were unreasonable. *Id.* at 1328-29. The Court explained that "Cisco's only assertion of invalidity over the prior art was based on anticipation by a reference that was twice considered and twice rejected by the Patent Office." *Id.* at 1328. And "its only non-infringement argument . . . was untethered to the district court's claim construction." *Id.* The Court additionally considered the fact that the jury found Cisco to be liable for induced infringement. *Id.* at 1329. The Court stated that, based on the unchallenged jury instructions relevant to inducement, it could "presume that the jury found that Cisco knew of the patent, took action to encourage its customers to infringe, and knew that its customers actions (if taken) would infringe." *Id.* The Court concluded that "the jury's unchallenged findings on induced infringement, when combined with Cisco's lack of reasonable bases for its infringement and invalidity defenses, provide sufficient support for the jury's finding of willful infringement for the period after May 8, 2012, when Cisco had notice of the patent." *Id.*

Here, there is undisputed evidence that Sage had knowledge of the '376 and '989 patents on the day each issued. Trial Tr. at 886:20-24. As in *SRI*, Sage asserted invalidity based solely on a reference (Van Den Heuvel) that was considered and rejected by the Patent Office. D.I. 342

at 12-13. And Sage advanced non-infringement positions that contradicted the Court's claim constructions. *Id.* at 11-12. Additionally, the jury here also found that Sage induced infringement of the asserted claims. D.I. 316 at 2. And as in *SRI*, the jury was instructed that, to find inducement, it must find that: (1) "Sage aided, instructed, or otherwise acted with the intent to cause acts by third parties that would constitute direct infringement of the asserted patents"; (2) "Sage knew of the patent at that time"; and (3) "Sage knew that the actions of third parties would infringe at least one asserted claim." D.I. 314 at 19. Thus, these findings combined with lack of reasonable bases for its defenses, provide sufficient support for the jury's willfulness verdict.

B. Sage's Pre-Issuance Conduct Supports the Jury's Willfulness Finding

Sage contends that its conduct before the '376 and '989 patents issued is wholly irrelevant to the issue of willful infringement. This makes no sense. According to Sage, it was free to copy PureWick's product and its confidential patent applications that gave rise to the patents-in-suit and engage in confidential discussions with PureWick and its counsel all to develop its own product. It could closely follow the prosecution of the applications it received and know, on the days the '376 and '989 patents issued, that what it copied was covered by those patents. Yet, despite all of that, it could escape a finding of willfulness because much of its bad behavior occurred before the patents issued. The law, however, does not incentivize pre-issuance copying.

It is well established that pre-issuance conduct may support a finding of willfulness. *WCM Indus., Inc. v. IPS Corp.*, 721 F. App'x 959, 970, n.4 (Fed. Cir. 2018)[14] (rejecting argument "that knowledge of a pending patent application cannot support a finding of willfulness"); *Minnesota Min. & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1581 (Fed. Cir. 1992)

[14] In *WCM,* the Federal Circuit distinguished cases decided prior to enactment of § 122(b)(1)(A), when parties were in "the dark … about prosecution activity." *Id.* The Court concluded that those "concerns are no longer valid when patent applications and realtime prosecution activity are published." *Id.*

("[P]re-patent conduct may also be used to support a finding of willfulness.").[15]

Pre-issuance copying, specifically, is relevant to the defendant's state of mind ***after issuance***. *Bioverativ Inc. v. CSL Behring LLC*, No. CV 17-914-RGA, 2020 WL 1332921, at *2 (D. Del. Mar. 23, 2020) ("Pre-patent copying of the invention, for example, is relevant to the defendant's state of mind after issuance."). This of course makes sense where, as here, an infringer had knowledge of the patents asserted against it on the day they issued and knew, as of that date, that what it copied is now covered by the scope of the issued claims.

Sage cites no contrary law. Sage, instead, misrepresents the law by crop-quoting *Sonos, Inc. v. D&M Holdings Inc.*, No. CV 14-1330-WCB, 2017 WL 5633204 (D. Del. Nov. 21, 2017), and ignoring the portions that undermine its argument. Sage asserts that *Sonos* stands for the broad proposition that "[e]vidence that the defendant copied the plaintiff's products prior to the issuance of the plaintiff's patent is inadmissible." D.I. 332 at 23-24. However, Sage crops out the Sage crops out the beginning of the quote, which states that only "[s]ome courts" have so held. *Sonos*, 2017 WL 5633204, at *3. And, Sage omits that *Sonos* explains that that other courts, ***including the Federal Circuit,*** have held otherwise:

> Other courts, including the Federal Circuit, have held that evidence that the defendant copied the plaintiff's products prior to the issuance of the plaintiff's patent is relevant to willfulness, at least in some circumstances.

2017 WL 5633204 at *3. Importantly, *Sonos* concluded such evidence was admissible. *Id.* at *2. The jury was entitled to consider Sage's pre-issuance conduct in concluding that Sage willfully infringed the '376 and '989 patents. *See* Section V.B, *infra*.

1. Substantial Evidence Supports a Finding of Copying

[15] *Kaufman Co. v. Lantech, Inc.*, 807 F.2d 970, 978–79 (Fed. Cir. 1986) (rejecting argument that evidence of pre-issuance copying could not be considered); *Apple Inc. v. Samsung Elecs. Co., Ltd.*, 258 F. Supp. 3d 1013, 1028 (N.D. Cal. 2017) (pre-issuance evidence of copying relevant).

Sage argues that the application (PTX-158) that it received from PureWick "does not include the same disclosure as the 376 patent." D.I. 332 at 23. At trial, however, the jury heard that Sage received PureWick's pending patent application, which matured into the asserted '989 patent. PTX-158.3. The evidence also demonstrated that the claims of the '376 patent were supported by the disclosure in the application Sage received. Trial Tr. at 433:12-439:18. A number of embodiments were the same. It therefore is irrelevant that the application did not include the small additional disclosure found in the '376 patent.

Second, Sage asserts that "the PrimaFit designer never saw any PureWick patent or patent application, much less a figure" (D.I. 332 at 23), referring to Ms. Blabas. But Sage is silent regarding Greg Davis, Director of Engineering in the New Product Development Group, who did receive PureWick's application. PTX-158.1-2. As discussed in PureWick's opening brief, the evidence showed that Mr. Davis dictated product design to Ms. Blabas, that he continually brought PrimaFit's development back to PureWick, and that Ms. Blabas abandoned her prior cup-shaped "designs" and moved to cylindrical designs with one point of suction, "like PureWick." D.I. 337 at 6-7. The jury saw Sage's "first viable concept" was nearly identical to Figure 38 of the '103 application and the asserted patents. *Compare* DTX-187.26, *with* '376 Patent, Fig. 38.

Third, Sage also asserts that "alleged copying of a figure in an application is irrelevant to showing knowing infringement of [a] later-issued patent claim[]." D.I. 332 at 23. But evidence that Sage copied Figure 38 of PureWick's application certainly is relevant where, as here, Dr. Collins testified that Figure 38 was encompassed by the scope of the claims of the '376 and '989 patents. *Compare* Trial Tr. at 435:24-439:18, *with id.* at 440:5-446:12.

Fourth, Sage also asserts that there was "no evidence that the PrimaFit engineer had access to any PureWick product." D.I. 332 at 25 (emphasis in original). But the jury received evidence

showing that PrimaFit's design engineer, Brett Blabas, had access to and tested PureWick's product. PTX-023; PTX-129; Trial Tr. at 211:12-24. Sage further asserts with there was no evidence that the PureWick product received by Sage was covered by the '376 and '989 patents. D.I. 332 at 24-26. Contrary to Sage's argument, the jury ***did*** hear evidence that Sage received the PureWick commercial silicone shell product and that this product is covered by the claims of the '376 and '989 patents. Specifically, the jury saw an email from a Sage employee to Dr. Newton stating that Sage was evaluating the functionality of PureWick's "new silicone wick." *See* DTX-403. Dr. Newton confirmed that PureWick sent Sage its silicone shell product, which was the same as PureWick's commercial embodiment (JTX-13). Trial Tr. at 259:13-25. And, as explained in more detail below in Section VIII, Dr. Collins testified that PureWick's commercial silicone shell embodiment, JTX-13, is was covered by the '376 and '989 patents.

Sage tries to excuse its copying as "ordinary 'competitive intelligence.'" D.I. 332 at 24, n.11. It is not "competitive intelligence" to copy another company's product and patent application in order to compete. Sage was not in the market before it copied, it copied to get into the market. If accessing PureWick's information was merely competitive intelligence, why did Sage allege it walled off Brett Blabas from people who provided her with that "intelligence?"

C. Sage's Post-Issuance Conduct Supports the Jury's Finding of Willfulness

Sage incorrectly argues that PureWick presented no evidence of Sage's post-issuance intent to infringe the '376 and '989 patents. D.I. 332 at 20. As explained above, the evidence showed that Sage had access to, and copied, PureWick's patent application and its commercial product during PrimaFit's development. Once the patents issued, Sage could not simply ignore that what it copied is what was patented. Thus, Sage's deliberate, pre-issuance copying provides substantial evidence of intentional infringement post-issuance. *Bioverativ,* 2020 WL 1332921 at *2.

Moreover, Sage learned of the '376 and '989 patents on the day each patent issued. Trial

Tr. at 886:20-24. Despite its immediate knowledge of the patents, Sage offered no evidence the company conducted a reasonable investigation, formed a good faith belief of non-infringement or invalidity, or obtained an opinion of counsel. Moreover, Mr. Alexander, "the primary attorney for the Sage business," admitted he was not aware of whether Sage had any policies about obtaining freedom to operate or advice of counsel opinions. *Id.* at 878:16-17, 887:12-20.

The jury also heard evidence that Sage continued to sell PrimaFit after learning that the '376 and '989 patents issued, and that it continued to instruct customers to use the PrimaFit in an infringing manner. *Id.* at 554:17-555:4. The jury credited PureWick's evidence, which further supports its determination that Sage willfully infringed the '376 and '989 patents after they issued. Sage's motion with respect to the jury's willfulness verdict should be denied.

VII. THE JURY PROPERLY AWARDED PUREWICK LOST PROFITS

"To recover lost profits a patentee must show that 'but for' infringement it reasonably would have made the additional profits enjoyed by the infringer." *Micro Chem., Inc. v. Lextron, Inc.,* 318 F.3d 1119, 1122 (Fed. Cir. 2003). "The *Panduit* and two-supplier market tests are recognized methods of showing 'but for' causation." *Id.* Under the two-supplier market test "a patentee must show: 1) the relevant market contains only two suppliers, 2) its own manufacturing and marketing capability to make the sales that were diverted to the infringer, and 3) the amount of profit it would have made from these diverted sales." *Id.* at 1124. The Court instructed the jury on both the *Panduit* factors and the two-supplier market test (Trial Tr. at 1130:16-1132:8).

The jury heard a great deal of evidence that the PureWick and PrimaFit products are the only two head-to-head competitors in the market for female external catheters. *Id.* at 364:14-365:8; PTX-69.56; PTX-719; PTX-36.5. Sage documents state that "PureWick is [Sage's] only competitor in this space when it comes to an external device for females." PTX-35; *see also* PTX-597.2 ("There is one competitor in the female external urine management space"). Similarly,

PureWick's witnesses testified that PureWick and PrimaFit were the only two products in the market. Trial Tr. at 196:10-13, 402:22-24, 550:4-552:10; PTX-107; PTX-399.35; PTX-719. And PureWick's damages expert, Dr. Leonard, testified that PureWick and PrimaFit compete head-to-head in a two-player market. Trial Tr. at 555:5-556:19.

Dr. Leonard also presented unrebutted testimony that PureWick had ample manufacturing capacity. *Id.* at 561:5-563:18; *see also* PTX-193.6. Dr. Leonard also presented unrebutted testimony that PureWick product was sold by the same sales teams that sell Bard's other urology products nationwide and thus had sufficient marketing capacity. Trial Tr. at 563:19-564:6. Finally, Dr. Leonard presented testimony of PureWick's incremental profits. *Id*. at 565:18-566:22.

This evidence more than sufficed to meet PureWick's burden under the two-supplier market test and, thus, the burden shifted to Sage to rebut the presumption of but for causation. *Micro Chem.*, 318 F.3d at 1125.

1. The Jury Rejected Sage's Purported Non-Infringing Alternatives

Sage asserts that "PureWick never refuted non-infringing PrimaFit design modifications and thus no reasonable jury could have found that there were no NIAs." D.I. 332 at 27 (emphasis in original). Because PureWick presented substantial evidence of a two-supplier market, however, the burden was on Sage to rebut the presumption of but for causation by showing that these alleged design arounds were available and acceptable. *Micro Chem.*, 318 F.3d at 1125. Furthermore, because Sage's alleged design arounds were never actually sold by Sage, it was Sage's burden to show that "Sage had all the necessary equipment, materials, know-how, and experience to design and manufacture the acceptable substitute." *See* Trial Tr. at 1133:11-19 (Court's jury instructions); *see also DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1331 (Fed. Cir. 2009) ("because [the defendant] did not actually have a noninfringing substitute 'on the market' during the relevant accounting period, it was [the defendant] that bore the burden of overcoming

the inference of unavailability."). Sage failed to satisfy either burden.

Sage's alleged NIA was "a version of the PrimaFit where the fabric layer was shortened so it did not extend across the entire top side of the device" that Brett Blabas contended she could have created. Trial Tr. at 606:18-607:23, 827:19-829:13. Neither Ms. Blabas nor Mr. Sheldon, however, pointed to any documents indicating that such a change was acceptable or that Sage had conducted any testing to evaluate its efficacy. In fact, Ms. Blabas did not testify that the proposed re-design of the product would have worked or been acceptable to customers. Sage's only evidence of the alleged acceptability of the design change was the conclusory testimony by Mr. Sheldon that "[i]t will not affect the fit and performance of the product." *Id.* at 829:7-11. The jury was entitled to reject the speculative and unsupported testimony, and it did.

Under Sage's view, infringers are entitled to posit any number of unsupported alleged NIAs and the jury must credit such assertions even when there is no proof such alleged alternatives would have functioned or been accepted in the market. This is not the law. *See, e.g.*, *AOS Holding Co. v. Bradford White Corp.*, No. CV 18-412-LPS, 2021 WL 5411103, at *36 (D. Del. Mar. 31, 2021) ("There is no persuasive evidence in the record that this design would have been acceptable to end users, either in terms of price or performance.").[16]

2. PureWick Appropriately And Conservatively Excluded Irrelevant Customers and Sales From Its Lost Profits Calculation

Sage argues that "[n]umerous other alternatives were on the market." D.I. 332 at 28. But PureWick proved that the alleged alternatives identified by Sage, such as diapers and absorbent pads, were not acceptable. Sage's own documents noted that these alternatives were totally

[16] *See also Grain Processing Corp. v. Am. Maize-Prod. Co.*, 185 F.3d 1341, 1353 (Fed. Cir. 1999) ("Mere speculation or conclusory assertions will not suffice to overcome the inference. After all, the infringer chose to produce the infringing, rather than noninfringing, product. Thus, the trial court must proceed with caution in assessing proof of the availability of substitutes not actually sold during the period of infringement.").

unacceptable. *See, e.g.*, PTX-42.4 ("Think of the alternative if the patient doesn't have a catheter, the patient is sitting in their urine and as you can imagine, patient dignity and comfort cannot be high for these patients."). The jury also heard evidence of why diapers and internal catheters were so problematic that no caring physician would willingly change back to those options from the patented invention. Trial Tr. at 413-14; *see also id.* at 350:15-352:10.

PureWick's experts, Dr. Leonard and Dr. Yun, both testified that these other urinary management products were not good substitutes because they did not offer the same benefits as the claimed inventions. *Id.* at 411:21-414:4, 550-553, 555-560. Dr. Yun testified that PureWick addressed substantial problems that existed with indwelling catheters and absorbent products for women (*id.* at 399:3-400:7) and that the other urine management products on the market identified by Sage do not provide the same benefits as PureWick and would not be used in place of a device like PureWick. *Id.* at 411:21-414:4. And Sage's own documents showed that the infringing PrimaFit product was specifically designed to address the problems associated with such prior devices. PTX-107.22; PTX-597.2; PTX-42.3; PTX-482.

Sage also argues that because "not all hospitals used PureWick or PrimaFit" supports a finding that there are acceptable NIAs. D.I. 332 at 28-29. The relevant inquiry, however, is whether there are available NIAs that would have been acceptable ***to customers in the relevant market***. *See Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, 702 F.3d 1351, 1361 (Fed. Cir. 2012). Indeed, what PureWick was required to prove was whether "but for" Sage's infringement ***the customers that purchased the infringing PrimaFit*** would have purchased the PureWick. We know that every PrimaFit customer chose the infringing/patented solution. The fact that another hospital had not yet adopted the invention is irrelevant as to whether the PrimaFit customers would have returned to diapers or internal catheters, or instead purchased PureWick.

Sage also argues that PureWick "acknowledged the existence of NIAs and the inability of PureWick to demonstrate sufficient marketing capability by excluding two customers" from the lost profits calculations, and also because there were "numerous examples of customers that did not want Bard's products because of quality issues." D.I. 332 at 28. The fact that certain customers did not want to purchase a product from PureWick, however, does not establish that there are acceptable NIAs or that PureWick lacked sufficient marketing capacity. As Dr. Leonard testified, he excluded from his lost profits calculation "some customer[s] that just for some reason had something about Bard that they just didn't like or had some kind of issue." Trial Tr. at 564:7-565:4. All that Dr. Leonard's testimony establishes is that for those specific customers he conservatively concluded that he could not definitively say that they would have bought PureWick. There is no evidence that had these excluded customers not been able to purchase PrimaFit they would have switched to a NIA. And, for the customers included in the lost profits calculation, Dr. Leonard testified that PureWick had the capacity to reach those customers. *Id.* at 563:19-564:6, 361:7 ("[W]e market to all hospitals"). At base, all these intensely factual questions were squarely in the province of the jury and, once again, the jury did not accept Sage's arguments.

3. Trial Evidence Established Demand for the Patented Product And There Was No Need for Apportionment

Sage argues "there was no evidence that demand was driven by a patented feature as opposed to other factors." D.I. 332 at 29. The relevant inquiry, however, is whether there is demand in the market for "a product 'covered by the patent in suit ***or that directly competes with the infringing device***.'" *Georgetown Rail Equip. Co. v. Holland L.P.*, 867 F.3d 1229, 1241-42 (Fed. Cir. 2017). "All a patentee must do is 'sell[ ] some item, the profits of which have been lost due to infringing sales.'" *Id.*; *see also Presidio*, 702 F.3d at 1360 ("[T]he demand in question in the first *Panduit* factor is not limited to demand for the patented products. Rather, demand may

arise from a product that 'directly competes with the infringing device.'").

PureWick presented substantial evidence of demand for the PureWick product, which is covered by the patents and directly competes with the infringing PrimaFit product. For example, PureWick proved demand based on the year-over-year sales increases for the PureWick. *See, e.g.*, PTX-799.6, 8; PTX-229.9; PTX-795; Trial Tr. at 361:8-364:12. Further, Mr. Gohde testified that PureWick is "the fastest growing new product that BD has ever had in its history" and "you can make a really good strong argument that it's a standard of care now . . . where there wasn't another solution available before PureWick." Trial Tr. at 379:12-23. PureWick also presented evidence of substantial sales of the infringing PrimaFit product. Trial Tr. at 565:5-17; DTX-751a-c; DTX199; PTX799.6; *see also Proctor & Gamble Co. v. Paragon Trade Brands, Inc.*, 989 F. Supp. 547, 601 (D. Del. 1997) ("[A] substantial number of sales of infringing products is compelling evidence of demand for the product.").[17]

Sage also argues that "PureWick's lost profits claim was never apportioned to account for the value of the 376/989 inventions."[18] D.I. 332 at 30. When the Panduit factors are met, however, "they incorporate into their very analysis the value properly attributed to the patented feature." *Mentor Graphics Corp. v. EVE-USA, Inc*., 851 F.3d 1275, 1287-90 (Fed. Cir. 2017) (holding that "the district court did not err in refusing to further apportion lost profits after the jury returned its verdict applying the Panduit factors" and rejecting the argument that the patentee must "further apportion its lost profits to cover only the patentee's inventive contribution.").

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[17] Sage's arguments that non-patented features of the PrimaFit, such as being latex-free, drove sales is misleading and irrelevant. For the relevant damages period PureWick always offered a latex-free option. Trial Tr. at 576:19-23. There is no proof that Sage would have sold a single PrimaFit that did not have the patented features.

[18] Sage failed to move before the case went to the jury for JMOL of no lost profits on the ground that PureWick had failed to apportion and, thus, Sage has waived the right to make the argument now. *Lightning Lube,* 4 F.3d at 1172-73.

VIII. SUBSTANTIAL EVIDENCE SUPPORTS THE JURY'S IMPLIED FACTUAL FINDING THAT PUREWICK'S PRODUCT IS COVERED BY THE PATENTS

Substantial evidence supports the jury's implied finding that the silicone shell PureWick product is covered by the '376 and '989 patents, especially when, as here, the record must be considered in the light most favorable to PureWick. Dr. Collins testified that PureWick's silicone shell wick was covered by each element of '376 patent claim 1, and its use was covered by each element of '989 patent claim 1. *See supra* Section V.A.2; Trial Tr. at 440:5-446:12. The jury also had the product itself, as well as the IFU for the PureWick product, which are on the product's packaging. JTX-13. The jury could examine the product and packaging and draw its own conclusions as to whether the product and its use are covered by the claims of the '376 and '989 patents. *See WCM Indus.*, 2016 WL 2755464, at *3; *Stryker Trauma*, 2007 WL 1959235, at *4.

Sage incorrectly argues that PureWick never adduced evidence that the PureWick product has a tube disposed in the reservoir. D.I. 332 at 29. To support that argument, Sage relies on a demonstrative, which is not evidence, and Dr. Collins' testimony on cross-examination affirming only that "the flexible porous material . . . extends past the tube" in PDX 4.3. *Id.* (citing Trial Tr. at 504-505). Neither prove its point. Indeed, when describing the product during his direct examination, Dr. Collins expressly testified that "the tube extends all the way down into what's called the reservoir area of the blue silicon[e] shell which you can see on the outside." Trial Tr. at 433:8-11, 433:2-12. Dr. Collins also confirmed that, when the PureWick product is used in accordance with its IFU, "the patient urinates, [and] it flows into this opening, down ***into this reservoir area where the extension of the tube is and removes the urine***." *Id.* at 431:14-19.

Sage also argues that PureWick never adduced evidence that the silicone shell product has a fluid impermeable layer coupled to the fluid reservoir as required by the first element of claim 1. D.I. 332 at 29. However, Dr. Collins specifically testified that the PureWick product met that

claim element, explaining "that outer cover has a fluid reservoir at the right end and then it has a fluid outlet at the other end, and that there is a longitudinally elongated opening in that casing which is between the fluid outlet and the fluid reservoir." Trial Tr. at 440:22-441:10. Dr. Collins also testified that the silicone shell met the last element of claim 1 of the '376 patent because, when a user "discharges urine from the urethral opening, ***it goes through the opening of the fluid impermeable layer*** into the membrane, through the membrane, through the support, into the reservoir." *Id.* at 444:3-12. Dr. Collins thus confirmed that the fluid impermeable casing—the blue silicone shell—has a fluid reservoir at the bottom end and a fluid outlet at its top end and the fluid impermeable layer extends between those two ends. Because the fluid impermeable layer is part of the silicone shell, and the silicone shell includes the fluid reservoir, the fluid reservoir is coupled to the fluid impermeable layer. Indeed, Ray Newton also confirmed that fact when he testified that, in the commercial PureWick silicone shell product, which was the same as the embodiment in PTX-656, the fluid impermeable silicone shell included a reservoir at the bottom end of the device. *See id.* at 303:2-22. The jury thus had before it substantial evidence showing that the silicone shell product has a fluid impermeable layer coupled to the fluid reservoir.

IX. SAGE'S CONDITIONAL MOTION TO AMEND THE JUDGMENT SHOULD BE DENIED

Sage cites no authority to support its argument that, should PureWick seek to amend the judgment to include claims and defenses withdrawn for case narrowing the Court should also enter judgment of noninfringement on claims not asserted at trial. D.I. 332 at 30. In any event, PureWick did not ask the court to enter judgment on the patent claims dropped for case narrowing purposes and, therefore, Sage's conditional motion should be denied.

X. CONCLUSION

PureWick respectfully requests that the Court deny all of Sage's post-trial motions.

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